DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 3, 2014

GE Medical Systems China Co., Ltd.
Kristin Pabst
Regulatory Affairs Manager
9900 West Innovation Dr.
Wauwatosa, Wisconsin 53226

Re: K142288
Trade/Device Name: MAC 800 Resting ECG Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: October 31, 2014
Received: November 3, 2014

Dear Kristin Pabst,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301)796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known):

Device Name: MAC 800 Resting ECG Analysis System

Indications for Use:

The MAC 800 is a portable ECG acquisition, analysis and recording system.
The MAC 800 is intended to be used under the direct supervision of a licensed healthcare practitioner.
The MAC 800 is intended to be used by trained operators in a hospital or medical professional's facility environment as well as used in clinics and physician offices outreach centers to record ECG signals from surface electrodes.
The MAC 800 is intended to acquire, analyze, display and record information from adult and pediatric populations. Pediatric population is defined as patients between the ages of 0 and 15 years.
The basic system shall provide 2 modes of operation: (1) Resting ECG mode and (2) Arrhythmia mode.
The basic systems shall print 3, 6-leads of ECG. The device shall be upgradeable to provide software options such as 12-lead ECG measurement and interpretive analysis.
Transmission and reception of ECG data to and from a central ECG cardiovascular information system shall be optional.
The arrhythmia detection portion of the MAC 800 is provided to the customer for the convenience of automatic documentation.

Contraindication:
The MAC 800 is not intended for use as a vital signs physiological monitor.
The MAC 800 is not intended for use during patient transport.
The MAC 800 is not suitable for intra cardiac application.
The MAC 800 is not designed to provide alarms for arrhythmia detection.

Prescription Use__X__ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: August 13, 2014

Submitted: Sun YanLi
Regulatory Affairs Manager
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Device: Trade Name: MAC 800 Resting ECG Analysis System
Common/Usual Name: Electrocardiograph
Classification Names: Electrocardiograph (21 CFR 870.2340)

Product Code: DPS
Predicate Device(s): MAC 800 Resting ECG Analysis System, K090212

MUSE Cardiology Information System K110132

12SL ECG Analysis Program K060833

Device Description:

The MAC 800 ECG acquisition, analysis and recording system can print and display multiple leads of ECG data. The MAC 800 will provide, in resting ECG mode, ECG quality information using the hookup advisor. The hookup advisor advises users of poor lead quality based on noise measurement. It can be upgraded

to provide options such as ECG measurement and interpretation with 12SL. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is also optional. Multiple QT correction formulas including Bazett, Framingham and Fridericia will be available as a user selectable option. Clinical Trials Data Guard and audit trail options are also available to support electronic record requirements.

The MAC 800 delivers multiple leads of ECG on full-size reports and includes an SMS/text message telephone keypad for patient demographics and other data entry with T9 input method, an integrated 7" color display, and an integrated thermal writer. The thermal writer will print real time continuous waveform, alphanumeric data and non-real time reports. The device can print the resting ECG report via the external laser printer including USB laser printer and network laser printer. The device will have optional internal memory and removable storage to store resting ECG records. The device also can export the resting ECG record to SD card/shared directory/FTP server as an optional function. An optional barcode reader and magnetic card scanner to enter patient information is available. The MAC 800 can be used as a portable unit.

Intended Use: The MAC 800 is a portable ECG acquisition, analysis and recording system.
The MAC 800 is intended to be used under the direct supervision of a licensed healthcare practitioner.
The MAC 800 is intended to be used by trained operators in a hospital or medical professional's facility environment as well as used in clinics and physician offices outreach centers to record ECG signals from surface electrodes.
The MAC 800 is intended to acquire, analyze, display and record information from adult and pediatric populations. Pediatric population is defined as patients between the ages of 0 and 15 years.
The basic system shall provide 2 modes of operation: (1) Resting ECG mode and (2) Arrhythmia mode.
The basic systems shall print 3, 6-leads of ECG. The device shall be upgradeable to provide software options such as 12-lead ECG measurement and interpretive analysis. Transmission and reception of ECG data to and from a central ECG cardiovascular information system shall be optional.
The arrhythmia detection portion of the MAC 800 is provided to

the customer for the convenience of automatic documentation.

Contraindication:
The MAC 800 is not intended for use as a vital signs physiological monitor.
The MAC 800 is not intended for use during patient transport.
The MAC 800 is not suitable for intra cardiac application.
The MAC 800 is not designed to provide alarms for arrhythmia detection.

Technology: The proposed MAC 800V2 Resting ECG Analysis System is a system based on the predicate MAC 800V1 (K090212) with improvements to the user experience.

The proposed MAC 800V2 Resting ECG Analysis System uses the same modes of operation including Resting ECG mode and Arrhythmia mode to do different ECG examinations, and uses 12SL ECG algorithm (K060833) to do ECG analysis. The major workflow and User Interface does not change. The proposed MAC 800V2 Resting ECG Analysis System provides identical Resting ECG mode and Arrhythmia mode as the predicate MAC 800V1 (K090212), and uses identical 12SL ECG algorithm (K060833).

The proposed MAC 800V2 Resting ECG Analysis System employs the same fundamental scientific technology as the predicate MAC 800V1 (K090212).

The MAC 800V2 is nearly identical to the MAC 800V1 system, with the addition of the updates and features described in this submission.

The proposed MAC 800V2 Resting ECG Analysis System is as safe and effective as the predicate devices.

The following table includes comparison of the main features of the device, and includes the features that are different from the predicate. Additional comparison information can be found in Comparison Matrix in Section 12.1.

Feature/Function	Proposed Device MAC 800 V2	Predicate Device MAC 800V1
Intended Use	MAC 800V2 intended use is the same as predicate MAC 800V1 with the exception of addition of expanded description to further clarify the medical professional's facility environment to include clinics, physician offices outreach centers. The main features of the device including (but not limited to) mechanical design, OS, ECG system performance, signal acquisition and input, ECG measurement parameters, arrhythmia features and optional software features are identical with predicate MAC 800V1. .	MAC 800V1 intended use is the same as proposed MAC 800V2 with the exception of MAC 800V2 expanded description to further clarify the medical professional's facility environment to include clinics, physician offices outreach centers. The main features of the device including (but not limited to) mechanical design, OS, ECG system performance, signal acquisition and input, ECG measurement parameters, arrhythmia features and optional software features are identical with proposed MAC 800V2. .
USB Port	2 USB ports Supports English: Keyboard, barcode and magnetic card reader, laser printer Supports French German, Italian and Spanish keyboards as well as USB WIFI card.	2 USB Ports Supports English: Keyboard, barcode and magnetic card reader, laser printer Not available
Supplies and Accessories	Supplies and accessories same as predicate except: Added a compact trolley Added USB WIFI card	Supplies and accessories same as proposed except: Compact trolley not available USB WIFI card not available

	2 ECG electrodes and clips removed due to end of life	
LCD panel	LED backlight to eliminate Hg for RoHS compliance	CCFL backlight
Anti-drift system	ADS arrhythmia mode ADS Rest mode	ADS Arrhythmia mode
Data Transmission routes	Wireless Lan data transmission 32 GB SD card.	Wireless Lan data transmission not available 2GB SD card
Communication Protocol	Same communication protocols as predicate except: Added GE designed DCP protocol to transfer ECG data.	Same communication protocols as proposed except: GE designed DCP protocol to transfer ECG data not available
Examination Order	Adds support for downloading and managing examination orders from the MUSE system	No support for downloading and managing examination orders from MUSE system
Data Export	Adds support to export and auto-export data to a FTP server 32 GB SD card	No support for export and auto-export data to FTP server 2GB SD card
Shared directory password/PDF file naming/File Management	Supports alphanumeric password for shared directory Auto-naming and user configurable naming of PDF files Adds *Preview* to existing file management functionality for enhanced data security and user convenience.	Supports numeric password for shared directory Auto-naming of PDF files *Preview* not available
Technique of Printout	USB laser printer Network laser printer Printer minimum memory capacity 8MB	USB laser printer Printer minimum memory capacity 2MB

Report formats for Laser Printer	Same report formats as predicate except: Adds 2 new ECG report layouts Adds a waveform distance auto-adjust for 12 lead printouts to avoid waveform overlap.	Same report formats as proposed except: 2 new ECG report layouts not available Waveform distance auto-adjust for 12 lead printouts not available
Service Tool	Ability to test network connection Ping IP test has been added for service purpose only	Ability to test network connection Ping IP test not available
Clinical Trials	5 pharma setting groups per user request Pop up message to notify "user ID already exists" when creating a non-unique user ID for clinical trial.	1 pharma setting group per user request "User ID already exists" pop up message not supported
Enhanced User experience	Ability to enable/disable automatic addition of leading "o" digits to patient ID entry Added printing of setup configuration file name in addition to saving and setup information content in a confiuration file, Ability to configure to synchonized clock when it has network connection to a time server.	Not available Printing of setup configuration file name not supported. Saving and set up inforamtin content in a configuration file Not available

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

The MAC 800V2 has been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with applicable voluntary standards has also been made to support safe use of the device in its intended environment.
The proposed MAC 800V2 and its applications were designed and tested for compliance to the following standards:

1. IEC 60601-1: 2005 + C1: 2006 + C2: 2007 Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

2. IEC 60601-2-25: 2011- Medical electrical equipment, Part 2-25: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographs.

3. IEC 60601-1-2: 2007–Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility

4. IEC 62304:2006, Medical devices - Medical device software – Software life cycle processes

5. IEC 62366: 2007–Medical devices-Application of usability engineering to medical device

6. ANSI/AAMI EC11: 1991/ (R2007)-Diagnostic Electrocardiographic Devices

Summary of Clinical Tests:

The subject of this premarket submission, the proposed MAC 800V2 did not require clinical studies to support substantial equivalence.

Conclusion:

The design changes made have no effect on the device's ability to acquire and analyze ECG data. GE Medical Systems *Information Technologies*, Inc. considers the proposed MAC 800V2 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.